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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,472	07/27/2001	Leland F. Wilson	9050-0013.23	4971

23980 7590 07/16/2004

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EXAMINER	
CRIARES, THEODORE J	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,472	WILSON ET AL.	
	Examiner	Art Unit	
	Theodore J. Criares	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-54 ARE PRESENTED FOR EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.117(e) had been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2004 has been entered with the following effect:

Applicant's arguments filed April 24, 2004 have been fully considered but they are not persuasive.

Applicants' argument that the truth of their specification is in question is not valid. The examiner has raised a doubt that all androgenic agents are capable of use as taught by applicants' specification. The teachings in Hutchinson et al and Mathew et al establish that a scientific doubt exists that androgentic agents would be effective to enhance sexual desire and responsiveness in a female individual. The Abstracts of articles forwarded to the Patent Office have been carefully reviewed. However, they cannot be conclusive since the full article was not sent for review and no definitive conclusion could be made from a review of the abstracts.

The protocol set forth by applicants is deemed insufficient to establish a valid opinion as to enablement under 35 U.S.C. §112, first paragraph. This is particularly true when applicants' comment on the Anastasiadis et al reference states that there is controversy with respect to the results of the use of androgens on the libido of females. There is a failure to disclose in the references what androgens were used and the amounts used. This latter information appears to be important since Apperloo et al indicates that low androgen levels cause low sexual desire.

The full articles should be presented to the Patent Office for review rather than merely the abstracts of each article since a definitive judgment cannot be made from a reading of only the abstract.

In view of the above the previous Office Action is deemed proper and repeated herein.

The applicants arguments are misdirected since pursuant to MPEP 2164 there is sufficient reasons of record to doubt the objective truth of the statements contained therein which must be relied on for enabling support. The applicants' claims are drawn to the use of androgenic agents to enhance sexual desire and responsiveness in a female individual.

This is the problem to be solved. However, the examiner has established that the prior art as illustrated by the Hutchinson et al and Mathew et al references that an androgenic agent, testosterone, is unlikely to have a place in the treatment of sexually unresponsive females.

The applicants' remarks also illustrate the state of the art is doubtful and unpredicatable. For example applicants admit that there is a problem to be solved to enhance sexual desire and response in a female. At page 11, last paragraph of number 1 it is admitted that as of the date of the filing of the subject application, the problem was still being addressed. The fact that a protocol of Example 9 is taught does not prove the fact that the problem and doubt as raised by the cited references is solved. At most it establishes that further undue experimentation is needed to determine if the problem is solved with the active agents claimed and taught by applicants.

The prior art as set forth by the examiner is sufficient reason that a doubt exists as to the agents claimed by applicant will enhance sexual desire and responsiveness in a female individual.

There is sufficient reason for doubt how to use applicants' invention See In re Marzocchi. 439 F2. 220, 169 USPQ 367 (CCPA 1971). Therefore, the burden is on the applicants to establish that androgenic agents are useful in enhancing the sexual desire and responsiveness in a female individual.

The previous Office Action is deemed proper and repeated herein as follows :

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the enhancing sexual desire and responsiveness in a female individual by administering androgenic agent in a chronic dosage regimen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors**

have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to enhancing sexual desire and responsiveness in a female individual by administering androgenic agent in a chronic dosage regimen. The nature of the invention is extremely complex in that it requires that female sexual desires be enhanced. The biological pathways involved in such enhancement is complex since it involves various hormones. Hutchinson et al. (BM) evidence this fact at pages 114s and 115s since they report that "(N)o evidence suggests that exogenous androgens play any role in the treatment of sexual dysfuction in the reproductive-aged women." Further, the complexity of the invention can be seen in Mathews et al (BN)reference which states in the Abstract that testosterone (an androgenic agent) is unlikely to have a useful place in the treatment of sexually unresponsive women.

Breath of the Claims: The complex of nature of the claims is greatly exacerbated by breath of the claims since they encompass a multitude of androgenic agents.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually enhance sexual desire in a female is limited. The examples only relate to a method by which the sexual desire can be determined but not the results of such tests. In other words the specification outlines a protocol but no results.

Working Examples: All of the working examples provided by the specification are directed toward the protocol.

State of the Art: The state of the art is that androgenic agents will not enhance sexual desire and the applicant has not provided data that provides the Examiner that all androgenic agents or reasonable representation thereof will enhance female sexual desires.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual enhancement of sexual desire in a female with the claimed compounds makes practicing the claimed invention unpredictable.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test. The combination in the model system to determine whether or not the agents are effective for enhancing sexual desire in a female If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding the ability of androgenic agents to enhance female sexual desire with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of

the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification or prior art regarding enhancing sexual desire in a female with any androgenic agent, the entire, unpredictable process would have to be repeated until successful.

Therefore, it would require undue, unpredictable experimentation to practice the claimed invention.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Theodore J. Criares
Primary Examiner
Art Unit 1617

7/13/04
tjc